

Notice of Agency Rule-making Proposal

AGENCY: Department of Health and Human Services, Division of Licensing and Regulatory Services, Medical Facilities Unit

RULE TITLE OR SUBJECT: Repeal and replace: Sentinel Events Reporting Rules. The new 10-144 C.M.R. Chapter 114, Rules Governing the Reporting of Sentinel Events, replaces the repealed sentinel events reporting provisions in: 10-144 C.M.R. Ch. 118, Regulations Governing the Licensing and Functioning of Intermediate Care Facilities for Persons with Mental Retardation [ICF-MR]; 10-144 C.M.R. Ch. 125, Regulations Governing the Licensing of Ambulatory Surgical Facilities; 10-144 C.M.R. Ch. 126, Regulations Governing the Licensing and Functioning of End Stage Renal Disease Units/Facilities [ESRD]; and 10-144 CMR Chapter 112, Regulations for the Licensure of General and Specialty Hospitals in the State of Maine [This notice also includes proposed hospitals rules.]

Repeal and replace: Hospital Licensing Rules. 10-144 CMR Chapter 112, Regulations for the Licensure of General and Specialty Hospitals in the State of Maine

PROPOSED RULE NUMBER: (LEAVE BLANK - ASSIGNED BY SECRETARY OF STATE):

CONCISE SUMMARY. Sentinel Events Reporting Rules. To reduce redundancy and streamline the rules, the new freestanding sentinel events reporting rules consolidate and replace the repealed sentinel events reporting provisions in 10-144 Chapters 112, 118, 125, and 126. The new sentinel events reporting rules introduce several proposed changes. Additional terms are defined, such as root cause analysis. Clarification regarding the reporting of rape is new and will assist providers to determine when a report is required. Clarification is also made with regard to who makes a final determination that an event is reportable. Section 2.7 requires an annual statement from health care facilities affirming that sentinel events that occurred during the prior calendar year were reported to the Sentinel Events Team (SET) in accordance with Section 2.2.

Hospital Licensing Rules. The proposed rules replace the current hospital licensing rules. Public Law 2007, Ch 314 streamlined the hospital survey process. Hospitals are exempt from state inspection requirements if they are federally certified by the Centers for Medicare and Medicaid Services [CMS] for participation in the federal Medicare program and hold full accreditation status by a health care facility accrediting organization recognized by CMS. Certified hospitals that are not accredited are subject to state inspection every 3 years. All hospitals remain subject to a state inspection in response to a complaint, suspected violation of hospital licensing laws and rules or suspected violation of the CMS conditions of participation. All hospitals remain subject to inspection to determine compliance with building codes, fire codes, life safety codes and for other similar purposes. At the hospital's request, the Department may review a hospital's architectural plans and a fee may be charged. Pursuant to Public Law 2007, Ch 324 hospital licenses may be renewed for up to 24 months. The rules are renamed "Rules for the Licensing of Hospitals".

THIS RULE **WILL NOT** HAVE A FISCAL IMPACT ON MUNICIPALITIES.

Economic impact on small businesses. [Applies to businesses with 20 or fewer employees.] Sentinel Events Reporting Rules. DHHS has determined that a new freestanding rule, 10-144 Ch 114 Regulations Governing the Reporting of Sentinel Events, that replaces the repealed sentinel events reporting provisions in 10-144 Chapters 112, 118, 125, and 125 can be implemented within the providers resources and no economic impact statement is required. Hospital Licensing Rules. DHHS has determined that the proposed hospital licensing rules will reduce the hospital's cost of compliance because there are fewer inspections and the standards are aligned with the federal CMS conditions of participation. These rules can be implemented within the provider's resources and no economic impact statement is required.

STATUTORY AUTHORITY: 22 M.R.S.A. §42; 22-A M.R.S.A. §205; 22 M.R.S.A. Chapter 1684; Public Law 2007, Chapters 314 and 324; and 22 MRSA Chapter 405.

PUBLIC HEARING: Monday, August 11, 2008 at 10 am, Conference Room, Division of Licensing and Regulatory Services, 41 Anthony Avenue, Augusta, Maine

DEADLINE FOR COMMENTS: Thursday, August 21, 2008 at 5 pm.

AGENCY CONTACT PERSON: Anne Flanagan, Assistant Director
AGENCY NAME: Division of Licensing and Regulatory Services
ADDRESS: 11 State House Station, 41 Anthony Avenue
Augusta, Maine 04333-0011
TELEPHONE: (207) 287-9300 fax (207) 287-5815 1-800-791-4080
TTY 1-800-606-0215
Anne.Flanagan@maine.gov

Please approve bottom portion of this form and assign appropriate MFASIS number.

APPROVED FOR PAYMENT _____ DATE: _____

Catherine M. Cobb, Director,
Division of Licensing and Regulatory Services

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